K082275

510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: January 13, 2010

JAN 14 2010

1. Submitter:

Submitted by:	Infopia Co.,ltd. #891,Hogye-dong, Dongan-Gu Anyang, Kyunggi 431-080, Korea Phone +82-31-460-0400 Fax +82-31-460-0401
Official Correspondent:	Maria Griffin mdi Consultants, Inc. 55 Northern Blvd., Ste. 200, Great Neck, NY 11021 516-482-9001
Company Contact:	Bryan Oh Phone: 1-321-267-9911 Fax: 1-321-267-5582

2. Device:

Propriety Name	CLOVER A1c ™
Common Name	Test system for hemoglobin A1c, blood glucose
Classification Name:	Glycosylated Hemoglobin test system Blood glucose test system
Classification:	Class II 21 CFR Part 864.7470 21 CFR Part 862.1345
Product Code:	CGA, LCP

3. Predicate Device:

DCA Vantage™, Test system for hemoglobin A1c, albumin and creatinine, K071466
Evolution™, Blood glucose monitoring system, K072369

4. Description:

The CLOVER A1c™ is a device which combines a Hemoglobin A1c monitoring system, and a blood glucose monitoring system.
The CLOVER A1c™ monitoring system includes Hemoglobin A1c Analyzer, Hemoglobin A1c Test cartridge, Hemoglobin A1c Check cartridge, Thermal printer, Barcode scanner, PC cable, and Fan filter.
The CLOVER A1c™ monitoring system is a fully automated boronate affinity assay for the determination of the percentage of hemoglobin A1c (HbA1c %) in human whole blood.

Hemoglobin A1c Test cartridge is composed of a cartridge and a reagent pack containing the reagents necessary for the determination of hemoglobin A1c, with a collection leg for blood sample collection.
The reagent pack is pre-filled with reaction solution and washing solution. The reaction solution contains agents that lyse erythrocytes and bind hemoglobin specifically, as well as a boronate resin that binds cis-diols of glycated hemoglobin.
Blood sample is collected at the collection leg of the reagent pack, and then the reagent pack is inserted into the cartridge. The assembled cartridge is inserted into the Hemoglobin A1c Analyzer and rotated so that the blood sample mixture is placed at the measurement zone of the cartridge, where the amount of total hemoglobin in the blood sample is photometrically measured. The measurement range is 4.0~14.0%. Acceptable anticoagulants for venous samples are EDTA, heparin, citrate and fluoride/oxalate.

The CLOVER A1c™ Glucose module is an in vitro diagnostic device designed for measuring the concentration of glucose in whole blood. The principle of the test replies upon a specific type of glucose in blood sample, the oxidase glucose that reacts to electrodes in the test strip. The test strip employs an electrochemical signal generation an electrical current that will stimulate a chemical reaction. This reaction is measured by the Meter and displayed as your blood glucose result.

5. Indications for use:

The CLOVER A1c™ HbA1c assay is an in vitro diagnostic test that quantitatively measures the percent concentration glycosylated hemoglobin in capillary or venous whole blood samples for clinical laboratory and point of care use. Measurement of percent HbA1c is used to monitor long-term glucose control in individuals with diabetes mellitus. CLOVER A1c™ is for in vitro diagnostic use and is not to be used for the diagnosis or screening of diabetes or for neonatal use.

The CLOVER A1c™ glucose assay is used for the quantitative measurement of the concentration of glucose in whole blood taken from the fingertip by healthcare professionals. The test is for prescription use as an aid in the management of diabetes. CLOVER A1c™ is for in vitro diagnostic use and is not to be used for the diagnosis or screening of diabetes or for neonatal use.

6. Comparison of Technological Characteristics with Predicate:

The CLOVER A1c™ has the same technological characteristics as the current legally marketed predicate devices, DCA Vantage ™ (K071466) by Siemens medical solutions diagnostics and Evolution ™ (K072369.) by Infopia Co., Ltd.

7. Performance Data:

Clinical: The clinical performance evaluation using the CLOVER A1c™ device was conducted for the purpose of validating the glycosylated hemoglobin and glucose measuring accuracy. Test results showed substantial equivalence.

Non-clinical: Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the CLOVER A1c™ with respect

to predicate devices. Pass or fail criteria were based on the specifications cleared for predicate devices and results showed substantial equivalence.

8. Conclusion:

The conclusion drawn from the clinical and non clinical tests is that the CLOVER A1c™ is as safe, as effective, and performs as well as the legally marketed predicate device, the DAC Vantage ™ and Evolution ™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Infopia Co., Ltd.
c/o Ms. Maria F. Griffin
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

JAN 14 2010

Re: k082275
Trade Name: Clover Alc™ Glycosylated Hemoglobin Monitoring System
Regulation Number: 21 CFR §864.7470
Regulation Name: Hemoglobin Alc Test System.
Regulatory Class: Class II
Product Codes: LCP, CGA
Dated: January 8, 2010
Received: January 11, 2010

Dear Ms. Griffin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K082275

Device Name: CLOVER A1c™ Glycosylated Hemoglobin Monitoring System

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Prescription Use ___X___ (21 CFR Part 801 Subpart D) And /Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K082275